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09/465,054	12/16/1999	DAVID BURTON	990326.ORI	8408

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EXAMINER

PATEL, MITAL B

ART UNIT PAPER NUMBER

3743

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/465,054

Applicant(s)

BURTON, DAVID

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32, 57-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32, 57-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments, filed 3/15/05, with respect to the rejection(s) of claim(s) 32, and 57-77 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, a new ground(s) of rejection is set forth below as necessitated by the amendment dated 3/15/05.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

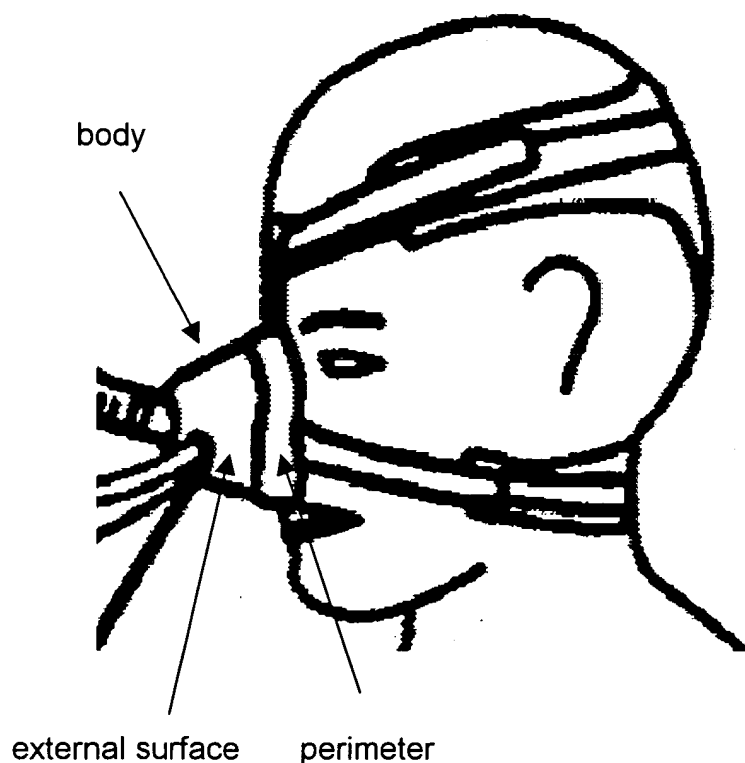
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 32, 57-61, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788) in view of Brown (US 6,000,395).

5. **As to claim 32**, Miles teaches a breathing mask **3,26** for monitoring a patient during gas delivery comprising a body (**See Fig. 2 attachment below**) having an internal surface (**inherent from Fig. 2 attachment below since mask is shown to be cupping the nose**), an external surface (**See Fig. 2 attachment below**), and a perimeter surface (**See Fig. 2 attachment below**) shaped to form a seal around the patient's nose; and at least one EEG sensor (**See Col. 4, lines 33-35; lines 44-45; lines 55-59; Col. 5, lines 6-15; and Col. 7, lines 37-51 which disclose a plurality and variety of sensors including an EEG sensor and further teach that the sensors may be mounted inside the mask or connected to the mask thereby reading on the limitation "extended from the mask"; it should also be noted that the physiological specific sensor is located on the respective/corresponding anatomy as shown in Fig. 2 and therefore, it would be obvious to one of ordinary skill in the art to place an EEG, which inherently measures/detects brain activity near or on the head and away from the mask in order to get a more precise reading**) extended from the mask and positioned to detect brain activity. Miles teaches essentially all of the limitations except for a headgear adapted to retain the body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed. Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific

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bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.



6. **As to claim 57**, the above combination teaches a breathing mask wherein the headgear is a cap (It should be noted that Brown teaches a headgear that is a cap).

7. **As to claim 58**, the above combination teaches essentially all of the limitations except for wherein the perimeter surface is adapted to detect ECG. Miles does teach an ECG lead **6** (**See Fig. 2**) placed over a patient's heart/chest area. However, it should be noted that Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including one that detects ECG, may be placed inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.

8. **As to claim 59**, the above combination teaches essentially all of the limitations except for further comprising a flow sensor connected to the internal surface. Miles does teach an airflow sensor (**See Col. 4, lines 33-35 and Col. 5, lines 20-21**). It should be noted that in Col. 5, lines 20-21, Miles teaches a flow sensor contained within the CPAP device; however, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a flow sensor, may be placed inside the mask or connected to the mask thereby providing an alternative placement of the sensor.

9. **As to claim 60**, the above combination teaches essentially all of the limitations except for a breathing mask further comprising an oxygen saturation sensor extended from the mask. Miles does teach an oxygen saturation sensor **5** but the oxygen

saturation sensor of Miles is placed on a finger rather than extending from the mask (See Fig. 2). However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an oxygen saturation sensor, may be placed inside the mask or connected to the mask thereby reading on the limitation "extended from the mask" and thus providing an alternative placement of the sensor.

10. **As to claim 61**, the above combination teaches essentially all of the limitations except for wherein the perimeter surface is adapted to detect eye movement. Miles does teach a sensor that detects eye movement (**See Col. 4, lines 33-37**). Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a sensor that detects eye movement, may be placed inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.

11. **As to claim 77**, Miles teaches a breathing mask **3,26** for monitoring a patient during gas delivery comprising a body (**See Fig. 2 attachment above**) having an internal surface (**inherent from Fig. 2 attachment above since mask is shown to be cupping the nose**), an external surface (**See Fig. 2 attachment above**), and a perimeter surface (**See Fig. 2 attachment above**) shaped to form a seal around the patient's nose; and at least one EEG sensor (**See Col. 4, lines 33-35; lines 44-45**;

lines 55-59; Col. 5, lines 6-15; and Col. 7, lines 37-51 which disclose a plurality and variety of sensors including an EEG sensor and further teach that the sensors may be mounted inside the mask or connected to the mask and therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to couple the EEG sensor to the body as providing an alternative placement for the sensors, which sensor would be capable of being positioned on a top portion of a patient's head upon application of the body to a patient).

Miles teaches essentially all of the limitations except for a headgear adapted to retain the body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed.

Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.

12. Claims 62-66, 68, 69, 70, 71, 73, 74, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788) in view of Brown (US 6,000,395).

13. As to claim 62, Miles teaches a nasal ventilation mask 3,26 comprising a body (See Fig. 2 attachment above) having an internal surface (inherent from Fig. 2 attachment above since mask is shown to be cupping the nose), an external surface (See Fig. 2 attachment above), and a perimeter surface (See Fig. 2 attachment above) adapted to form a seal around a patient's nose (See Fig. 2 attachment above), an air hose 2 extending from the body; and at least one EMG sensor (chin) (See Col. 7, lines 39-40). It should be noted that Miles also teaches that that some of the sensors may be mounted inside or connected to the mask (See Col. 4, lines 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an EMG (chin) sensor, may be placed inside the mask or connected to the mask thereby providing an alternative placement of the sensor and thus be capable of detecting muscle activity relating to a sleep state as recited. Miles teaches essentially all of the limitations except for a headgear adapted to retain the body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed. Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal

and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.

14. **As to claim 63**, Miles teaches essentially all of the limitations including a first sensor for detecting nasal breathing (**See Col. 5, lines 12-14**) and a second sensor for detecting oral breathing (**See Col. 7, lines 41-42**) except for the location of the sensors. It should be noted that Miles also teaches that that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors may be placed inside the mask or connected to the mask thereby providing an alternative placement for the sensors.

15. **As to claim 64**, Miles teaches a mask wherein the first and second sensors are thermal sensors (**See Col. 5, lines 12-14 and See Col. 7, lines 41-42**).

16. **As to claim 65**, Miles teaches essentially all of the limitations including an EEG sensor (**See Col. 4, lines 33-35; lines 55-59; Col. 5, lines 6-15; and Col. 7, lines 37-51**) except for the EEG sensor positioned on the perimeter surface. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an EEG sensor, may be placed inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.

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17. **As to claim 66**, Miles teaches essentially all of the limitations including an EOG sensor (**See Col. 4, lines 36-37; lines 55-59; and Col. 7, line 39**) except for the EOG sensor positioned on the perimeter surface. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an EOG sensor, may be placed inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.

18. **As to claim 68**, Miles teaches essentially all of the limitations including a plurality of straps (**See Fig. 2**) except for the straps having at least one sensor positioned thereon. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, may be placed inside the mask or connected to the mask (the straps being connected to the mask) to provide an alternative placement of the sensor.

19. **As to claim 69**, Miles teaches essentially all of the limitations including a position sensor (**See Col. 4, line 58 which discloses overall physical movement which the Examiner considers equivalent to a position sensor since a position sensor would detect any movement or lack thereof; See also Col. 7, lines 46-49**) except for the position sensor positioned on the perimeter surface. However, Miles also teaches

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that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a position sensor, may be placed inside the mask or connected to the mask to provide an alternative placement of the sensor.

20. **As to claim 70**, Miles teaches essentially all of the limitations including a microphone **10** (**See also Col. 7, lines 42-43**) except for the microphone coupled to the body. However, Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including a microphone which would sense breathing and snoring, may be placed inside the mask or connected to the mask to provide an alternative placement of the microphone.

21. **As to claim 71**, Miles teaches essentially all of the limitations including a sensor to detect air leaks (**Please note, Col. 4, lines 35-36 and line 56; Col. 5, lines 22-31; and Col. 7, lines 41-44 teach an airflow sensor and a pressure sensor which would indirectly sense air leaks should there be a pressure drop which would also effect the airflow**) except for the location of such a sensor on the perimeter surface. However, it should be noted that Miles also teaches that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including one senses air leaks

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via a airflow sensor or pressure sensor, may be placed inside the mask or connected to the mask (a perimeter surface is encompassed by the disclosure) to provide an alternative placement of the sensor.

22. **As to claim 73**, Miles teaches a nasal ventilation mask **3,26** (**See Fig. 2 attachment above**) adapted to form a seal around a patient's nose (**See Fig. 2 attachment above**), an EEG sensor (**See Col. 4, line 59 and Col. 7, line 39**). Miles teaches essentially all of the limitations except for a headgear adapted to retain the body on the patient's head, the headgear having at least one EEG sensor positioned thereon. Brown teaches the use of a headgear with sensors placed strategically thereon so that the particular bodily condition of the user may be sensed. Therefore, it would have been obvious to one of ordinary skill in the art to provide a headgear in the breathing mask of Miles so that specific body sensors such as an EEG sensor may be placed strategically on the appropriate anatomy of the human being to sense that specific bodily condition as taught by Brown. Furthermore, it would have been obvious to one of ordinary skill in the art that an EEG sensor be placed on or near the head to detect the appropriate signal and as such it would have been further motivation to provide the EEG sensor on a headgear type device to hold the sensors in place in conjunction with the mask.

23. **As to claim 74**, Miles teaches a mask **3,26** furthering comprising a computer **25** in communication with the sensor, the computer adapted to determine arousal (**See Col. 4, lines 32-66; please note the Examiner considers overall physical**

movement, leg movement, eye movement, EEG all to detect some form of arousal).

24. **As to claim 75**, Miles teaches a mask **3,26** furthering comprising a computer **25** in communication with the sensors, the computer adapted to determine sleep state (**See Col. 4, lines 32-66; please note the Examiner considers breathing sounds, overall physical movement, leg movement, eye movement, EEG, sleep position all to detect some form of sleep state**).

25. **As to claim 76**, Miles teaches a mask further comprising an EMG sensor (chin) (**See Col. 7, lines 39-40**). Miles does not explicitly teach the EMG sensor coupled to the nasal mask. However, it should be noted that Miles also teaches that that some of the sensors may be mounted inside or connected to the mask (**See Col. 4, lines 44-45**). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention and based on the disclosure by Miles that the sensors, including an EMG (chin) sensor, may be placed inside the mask or connected to the mask thereby providing an alternative placement of the sensor.

26. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788) in view of Brown (US 6,000,395) and further in view of Bornn (US 5,353,793).

27. **As to claim 67**, Miles and Brown teach essentially all of the limitations except for wherein a portion of the perimeter is comprised of a conductive carbonized rubber material. It should be noted that Bornn does teach the use of physiological sensors such as ECG, piezoelectric sensors for monitoring respiration and pulse, temperature

sensors, and activity and position sensor, which come into contact with the patient's skin. Bornn further provides a conductive carbonized rubber material (**See Col. 7, lines 34-37 of Bornn**) for providing electrical contact between a person's skin and the sensor. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a portion of the perimeter surface with a conductive carbonized rubber material as taught by Bornn to provide an electrical contact between a person's skin and the sensor since Miles discloses that the sensors may be mounted inside the mask (which would include a portion of the perimeter surface).

28. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788) in view of Brown (US 6,000,395) and further in view of Wiesmann et al (US 6,199,550).

29. **As to claim 72**, Miles and Brown teach essentially all of the limitations except for the mask further comprising a patient recycled air detection system positioned on the internal surface. Wiesmann et al teaches a mask with sensors including a sensor which monitors exhaled carbon dioxide (**See Col. 5, line 42**) located on the internal surface of the mask (**See Fig. 3 of Wiesmann et al**). It should be noted that the sensor of Wiesmann et al is equivalent in scope to the recycled air detection system of Applicant since Applicant on page 10 of the specification discloses that the air detection system has a sensor that detects the amount of expired air from the patient remaining in the mask. The Wiesmann et al sensor monitors the exhaled carbon dioxide and would also indirectly detect any remaining exhaled air in the mask since the Wiesmann sensor is located on the interior of the mask. Therefore, it would have been obvious to one of

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ordinary skill in the art at the time of the invention to provide a sensor that monitors exhaled carbon dioxide in the mask of Miles as taught by Wiesmann et al so that the amount of air exhaled by the patient would be detected by the sensor and indirectly measure the exhaled air remaining in the mask.

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mital B. Patel
Examiner
Art Unit 3743